

ATENT COOPERATION TF TY

From the INTERNATIONAL BUREAU

PCT**NOTIFICATION OF ELECTION**

(PCT Rule 61.2)

Date of mailing (day/month/year)
09 April 2001 (09.04.01)

To:
**Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE**
in its capacity as elected Office

International application No.
PCT/IB00/01066

Applicant's or agent's file reference
W/D/135

International filing date (day/month/year)
31 July 2000 (31.07.00)

Priority date (day/month/year)
30 July 1999 (30.07.99)

Applicant

GODFRIED, Herman, Philip

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

13 February 2001 (13.02.01)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Pascal Piriou

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

Date of mailing (day/month/year) 10 April 2002 (10.04.02)
Applicant's or agent's file reference W/D/135
International application No. PCT/IB00/01066

To: BULL, Christopher, Michael Spoor and Fisher P.O. Box 41312 2024 Craighall AFRIQUE DU SUD

IMPORTANT NOTIFICATION				
1. The following indications appeared on record concerning: <input checked="" type="checkbox"/> the applicant <input type="checkbox"/> the inventor <input type="checkbox"/> the agent <input type="checkbox"/> the common representative				
Name and Address DRUKKER INTERNATIONAL B.V. Beversstraat 20 NL-5431 SH Cuijk Netherlands	State of Nationality NL		State of Residence NL	
	Telephone No.			
	Facsimile No.			
	Teleprinter No.			
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning: <input type="checkbox"/> the person <input checked="" type="checkbox"/> the name <input type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence				
Name and Address DRUKKER INTERNATIONAL BV Beversstraat 20 NL-5431 SH Cuijk Netherlands	State of Nationality NL		State of Residence NL	
	Telephone No.			
	Facsimile No.			
	Teleprinter No.			
3. Further observations, if necessary: Telephone: 31-485-395-700, Fax: 31-485-316-104, E-mail: xiao.tang@druckerint.nl				
4. A copy of this notification has been sent to: <input checked="" type="checkbox"/> the receiving Office <input type="checkbox"/> the designated Offices concerned <input type="checkbox"/> the International Searching Authority <input checked="" type="checkbox"/> the elected Offices concerned <input type="checkbox"/> the International Preliminary Examining Authority <input type="checkbox"/> other:				

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Akiko KOYAMA Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

10/04/81
 CORRECTED
 VERSION
 PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

Date of mailing (day/month/year) 10 April 2002 (10.04.02)
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From the INTERNATIONAL BUREAU

To:

BULL, Christopher, Michael
Spoor and Fisher
P.O. Box 41312
2024 Craighall
AFRIQUE DU SUD

Applicant's or agent's file reference W/D/135
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IMPORTANT NOTIFICATION

International application No. PCT/IB00/01066

International filing date (day/month/year) 31 July 2000 (31.07.00)

1. The following indications appeared on record concerning:

the applicant the inventor the agent the common representative

Name and Address

State of Nationality	State of Residence
----------------------	--------------------

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

the person the name the address the nationality the residence

Name and Address

State of Nationality	State of Residence
----------------------	--------------------

GILSON, David, Grant
Spoor & Fisher
Rochester Place, Block A
173 Rivonia Road
Morningside
2024 Sandton
South Africa
(Applicant for IS only)

ZA

ZA

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

This form replaces and cancels Form PCT/IB/306 issued on 4 February 2002.

4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Akiko KOYAMA

Telephone No.: (41-22) 338.83.38

101028131

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

Date of mailing (day/month/year)
04 February 2002 (04.02.02)

From the INTERNATIONAL BUREAU

To:

BULL, Christopher, Michael
Spoor and Fisher
P.O. Box 41312
2024 Craighall
AFRIQUE DU SUD

<p>Applicant's or agent's file reference W/D/135</p> <p>International application No. PCT/IB00/01066</p>	IMPORTANT NOTIFICATION
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1. The following indications appeared on record concerning:

the applicant the inventor the agent the common representative

Name and Address 	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

the person the name the address the nationality the residence

Name and Address GILSON, David, Grant Spoor and Fisher Rochester Place, Block A 173 Rivonia Road Morningside 2196 Sandton South Africa	State of Nationality ZA	State of Residence ZA
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

Additional applicant for the purpose of IS only.

4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer R. Raissi Telephone No.: (41-22) 338.83.38
---	---

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference W/D/135	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IB 00/01066	International filing date (day/month/year) 31/07/2000	(Earliest) Priority Date (day/month/year) 30/07/1999
Applicant DRUKKER INTERNATIONAL B.V. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing :
- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. Certain claims were found unsearchable (See Box I).

3. Unity of invention is lacking (see Box II).

4. With regard to the title,

- the text is approved as submitted by the applicant.
- the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- the text is approved as submitted by the applicant.
- the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

- as suggested by the applicant.
- because the applicant failed to suggest a figure.
- because this figure better characterizes the invention.

None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 00/01066

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 622 966 A (BEARD) 18 November 1986 (1986-11-18) column 2, line 5 - line 15; figure 3 ---	1-3, 7-9
Y	US 5 376 099 A (ASSIL KERRY K ET AL) 27 December 1994 (1994-12-27) column 4, line 29 - line 36; figure 3 ---	7-9
Y	WO 98 21747 A (ENDO SHUNICHI ;NAKASE RISA (JP); TOZAWA MASAKI (JP); AKAHORI TAKAS) 22 May 1998 (1998-05-22)	1-3
A	abstract ---	7, 10
A	US 4 697 489 A (KIM GEORGE A) 6 October 1987 (1987-10-06) column 2, line 52 - line 62; figure 2 ---	7-9
	-/-	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 October 2000	27/10/2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patenttaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016	Authorized officer Ducreau, F

INTERNATIONAL SEARCH REPORT

Application No
PCT/IB 00/01066

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 1997, no. 01, 31 January 1997 (1997-01-31) & JP 08 236517 A (NEC CORP), 13 September 1996 (1996-09-13) abstract ---	1,7,10
A	US 3 786 814 A (ARMAO T) 22 January 1974 (1974-01-22) column 6, line 33 -column 7, line 7 column 3, line 25 -column 4, line 30 column 2, line 10 - line 19 ---	1,7,10
A	GB 2 060 397 A (SHAW R F) 7 May 1981 (1981-05-07) page 3, line 15 - line 28; figure 2 abstract ---	1,7,10
A	US 5 480 398 A (EGGERS PHILIP E) 2 January 1996 (1996-01-02) column 7, line 60 -column 8, line 24 ---	1,2,7,8, 10
A	PATENT ABSTRACTS OF JAPAN vol. 1999, no. 07, 31 March 1999 (1999-03-31) & JP 09 246264 A (INTERNATL BUSINESS MACH CORP <IBM>), 19 September 1997 (1997-09-19) abstract ---	1,7,10
P,A	& US 5 942 328 A 24 August 1999 (1999-08-24) ----	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.
PCT/IB 00/01066

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4622966	A	18-11-1986	US 4481057 A AU 552383 B AU 7651481 A CA 1178867 A CA 1200167 C DE 3140671 A FR 2492721 A GB 2085765 A,B NL 8104881 A	06-11-1984 29-05-1986 06-05-1982 04-12-1984 04-02-1986 16-06-1982 30-04-1982 06-05-1982 17-05-1982
US 5376099	A	27-12-1994	AU 5452994 A EP 0746243 A MX 9306744 A WO 9409710 A	24-05-1994 11-12-1996 29-04-1994 11-05-1994
WO 9821747	A	22-05-1998	JP 10144675 A	29-05-1998
US 4697489	A	06-10-1987	US 4581969 A CH 669355 A EP 0167330 A IL 75560 A JP 1758547 C JP 4043228 B JP 61035330 A US 4643161 A	15-04-1986 15-03-1989 08-01-1986 30-10-1987 20-05-1993 15-07-1992 19-02-1986 17-02-1987
JP 08236517	A	13-09-1996	JP 2748879 B CA 2157257 A EP 0701283 A KR 188573 B US 5698901 A US 6033979 A	13-05-1998 13-03-1996 13-03-1996 01-06-1999 16-12-1997 07-03-2000
US 3786814	A	22-01-1974	NONE	
GB 2060397	A	07-05-1981	AU 6166380 A BR 8005831 A CA 1161326 A DE 3031049 A FR 2469174 A JP 1676537 C JP 3034939 B JP 56045648 A NL 8004670 A SE 449431 B SE 8006253 A US 4848337 A ZA 8004849 A	19-03-1981 24-03-1981 31-01-1984 02-04-1981 22-05-1981 26-06-1992 24-05-1991 25-04-1981 12-03-1981 04-05-1987 11-03-1981 18-07-1989 26-08-1981
US 5480398	A	02-01-1996	AU 5326994 A WO 9408520 A AU 677207 B AU 4370193 A EP 0637941 A JP 8500025 T WO 9321839 A US 5593406 A US 5480397 A	09-05-1994 28-04-1994 17-04-1997 29-11-1993 15-02-1995 09-01-1996 11-11-1993 14-01-1997 02-01-1996

INTERNATIONAL SEARCH REPORT

on patent family members

Int'l Application No
PCT/IB 00/01066

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 5480398 A		US	5496314 A	05-03-1996
JP 09246264 A	19-09-1997	US	5942328 A	24-08-1999
		US	5945155 A	31-08-1999
		US	5942769 A	24-08-1999

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference W/D/135	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IB 00/01066	International filing date (day/month/year) 31/07/2000	(Earliest) Priority Date (day/month/year) 30/07/1999
Applicant DRUKKER INTERNATIONAL B.V. et al.		

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- because the applicant failed to suggest a figure.
- because this figure better characterizes the invention.

None of the figures..

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	WO 98 21747 A (ENDO SHUNICHI ;NAKASE RISA (JP); TOZAWA MASAKI (JP); AKAHORI TAKAS) 22 May 1998 (1998-05-22)	03 1-3
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A	US 4 697 489 A (KIM GEORGE A) 6 October 1987 (1987-10-06) column 2, line 52 - line 62; figure 2 ---	7-9 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 October 2000	27/10/2000

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Ducreau, F

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5 480 398 A (EGGERS PHILIP E) O 2 2 January 1996 (1996-01-02) column 7, line 60 -column 8, line 24 ---	1,2,7,8, 10
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P,A		

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International Application No

PCT/IB 00/01066

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Information on patent family members

International Application No

PCT/IB 00/01066

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
US 5480398 A		US	5496314 A	05-03-1996
JP 09246264 A	19-09-1997	US	5942328 A	24-08-1999
		US	5945155 A	31-08-1999
		US	5942769 A	24-08-1999

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

INPROMA	
Entered	S.V.
Draw file	<input checked="" type="checkbox"/> Y <input type="checkbox"/> N

To:

GILSON, David Grant
SPOOR & FISHER
PO Box 41312
2024 Craighall
AFRIQUE DU SUD

SPOOR & FISHER

2001 -11- 8 -

SEEN
MAIL
INPROMA
ENTERED BY

Date of mailing
(day/month/year) 02.11.2001

Applicant's or agent's file reference
PA129340/PCT

IMPORTANT NOTIFICATION

International application No.
PCT/IB00/01066

International filing date (day/month/year)
31/07/2000

Priority date (day/month/year)
30/07/1999

Applicant

DRUKKER INTERNATIONAL B.V. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer

Edel, M

Tel.+49 89 2399-2426



PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PA129340/PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB00/01066	International filing date (day/month/year) 31/07/2000	Priority date (day/month/year) 30/07/1999
International Patent Classification (IPC) or national classification and IPC A61B17/32		
Applicant DRUKKER INTERNATIONAL B.V. et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application 		

Date of submission of the demand 13/02/2001	Date of completion of this report 02.11.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Péru, L Telephone No. +49 89 2399 2377



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB00/01066

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-11 as originally filed

Claims, No.:

1-15 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB00/01066

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- restricted the claims.
- paid additional fees.
- paid additional fees under protest.
- neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- complied with.
- not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- all parts.
- the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-15
No: Claims

Inventive step (IS) Yes: Claims
No: Claims 1-15

Industrial applicability (IA) Yes: Claims 1-15
No: Claims

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB00/01066

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

IV. Unity

Claim 1 deals with a method of forming a protective layer of fluorine wherein the fluorine is put by plasma reaction; Claim 10 deals with a method of forming a protective layer of fluorine wherein the fluorine is put by immersion.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) since the two processes have nothing in common and the presence of a protective layer of fluorine atoms in itself is known.

V. Novelty and inventive step

- 1 Document US-A-5 376 099 (**D1**) discloses (claims) a cutting blade for a surgical instrument, the cutting blade being formed of a hard, transparent, crystalline material, e.g. diamond, which may be natural or synthetic.
Document US-A-5 480 398 (**D2**) discloses (column 8 lines 11-12) that a coating is suitable on surgical instrument for avoiding adherence, this coating being made of a fluorine-containing mixture (see also abstract of GB-A-2 060 397).

In view of the teaching of both documents, the skilled person would regard it a normal design procedure to combine all the features set out in claims 7-9, namely providing a protective layer of fluorine atoms on the surface of a known blade.
(See part VIII for the process feature)

Thus, the subject-matter of claims 7-9 does not involve an inventive step and does not satisfy the criterion set forth in Article 33.3 PCT.

- 2 Document WO 98/21747 (**D3**) discloses a method of forming a protective layer of fluorine atoms comprising the steps of placing the object to be covered in a plasma reactor, plasma cleaning the object and coating it in a plasma of carbon fluoride gas. The carbon fluoride may be C_3F_8 , C_2F_4 or C_2F_6 , the coating taking place at a pressure of 0.01 to 2 mbar for a period of 30 to 180 min at a power level of 50 to 2000 W, in a plasma of air, oxygen or argon.
The method itself as defined in claims 1, 3, 5-6 thus is not novel.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB00/01066

Concerning the chemical cleaning of the blade, it is obvious that the object to be coated is always cleaned prior to be coated, the chemical cleaning being one of the straightforward possibilities.

The subject-matter of claims 1-6 differs therefrom only in the specification of the object to be coated, which does not provide any restriction to the method as such. Moreover, since document D2 already gives a strong indication that it would be suitable to cover a [known] surgical blade with fluorine, the person skilled in the art would, without any inventive skill, apply the method known from D3.

The subject-matter of claims 1-6 thus does not involve an inventive step (Article 33.3 PCT).

- 3 Document US-A-5 760 126 (**D4**) discloses a method of forming a protective layer of fluorine atoms comprising the step of immersing the object to be covered into a solution of a fluoroaliphatic silyl ether (abstract, column 2 lines 42-61 and column 3 lines 50-55).

Similarly as above in item 2, the choice of this method, known as providing a hard coating with high abrasion resistance, for use with known blades does not involve an inventive step so that the subject-matter of claims 10-11 does not meet the requirements of Article 33.3 PCT.

Document D4 also discloses the step of forming a hydroxyl terminated surface on the object to be coated, or of providing a silicon layer on it (column 4 lines 58-61). The parameters given in claims 12 and 15 are matter of normal design possibilities.

Claims 12-15 do neither meet the requirements of article 33.3 PCT.

VII. Other remarks

- 1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D4 is not mentioned in the description, nor are these documents identified therein.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB00/01066

- 2 Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (see part V) being placed in a preamble and with the remaining features being included in a characterising part.
- 3 The mentions "incorporated by reference" (pages 2 and 6) are not accepted by all Examination Authorities and should have been deleted; the provisional numbers on pages 2 and 11 should have been replaced by the publication numbers (PCT Guidelines II-4.17).

VIII. Clarity

- 1 Product claim 7 attempts to define its subject-matter by the process of manufacturing it. It is not clear what specific technical characteristics this process implies for the product itself and how the way of producing would restrict the device itself in terms of product features.
- 2 Claims 2 and 11 deal with characteristics of the blade, which does not restrict the method defined in the independent claims on which they depend.
- 3 The statement in the description on page 6 (last paragraph) wherein other processes are mentioned to achieve the layer of fluorine atoms, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

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PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PA129340/PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB00/01066	International filing date (day/month/year) 31/07/2000	Priority date (day/month/year) 30/07/1999
International Patent Classification (IPC) or national classification and IPC A61B17/32		
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**INTERNATIONAL PRELIMINARY
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International application No. PCT/IB00/01066

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- 3 Document US-A-5 760 126 (**D4**) discloses a method of forming a protective layer of fluorine atoms comprising the step of immersing the object to be covered into a solution of a fluoroaliphatic silyl ether (abstract, column 2 lines 42-61 and column 3 lines 50-55).
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VII. Other remarks

- 1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D4 is not mentioned in the description, nor are these documents identified therein.

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International application No. PCT/IB00/01066

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(71) Applicant (*for all designated States except US*):
DRUKKER INTERNATIONAL B.V. [NL/ZA]; Debid House, Corner Amethyst Street And Crownwood Road, Theta, 2001 Johannesburg (ZA).

(72) Inventor; and

(75) Inventor/Applicant (*for US only*): **GODFRIED, Herman, Philip [NL/NL]**; Dalkruid 57, NL-7491 LP Delden (NL).

(74) Agents: **BULL, Christopher, Michael et al.**; Spoor and Fisher, Rochester Place, 173 Rivonia Road, Morningside, Sandton (ZA).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 01/08570 A1

(54) Title: A CUTTING BLADE FOR A SURGICAL INSTRUMENT

(57) Abstract: This invention relates to a method of forming a protective layer of fluorine atoms on a cutting blade of a surgical instrument in which the blade is formed of a hard, transparent, crystalline material such as diamond, sapphire or garnet. According to the method the blade is placed in a plasma reactor, the blade is then plasma cleaned and coated with a plasma of carbon fluoride gas. The invention also relates to a method of forming a protective layer of fluorine atoms on a blade for surgical instruments in which the blade is immersed into a solution of fluoroaliphatic silyl ether.

5C Rec'd PCT/Pt. 23 JAN 2002

WO 01/08570

PCT/IB00/01066

- 1 -

A CUTTING BLADE FOR A SURGICAL INSTRUMENT

BACKGROUND TO THE INVENTION

THIS invention relates to a cutting blade for a surgical instrument in which the cutting blade is formed of a hard transparent, crystalline material, such as diamond sapphire or garnet, on the surface of which is provided a layer of fluorine atoms chemically bonded to the surface.

Surgical blades are extremely sharp in order to minimise tissue damage along a line of incision. In order to achieve the desired sharpness of a cutting blade materials of choice for the manufacture of cutting blades are hard materials of a crystalline nature, such as diamond or sapphire.

During use blood and other bodily fluids and materials often stick to the facets of a cutting blade thereby reducing its effectiveness. It is known to prevent this from happening or at least reduce the sticking effect and facilitate cleaning of the blade by, for instance, wiping the blade with a suitable material or sticking it into a block of suitable plastic foam, for example polystyrene.

The problem of blood sticking to or coagulating on the surface of a cutting blade may be aggravated under conditions where coagulation of blood is promoted. This may be caused by deliberate heating of the surgical blade to induce coagulation; by high intensity light sources used in conjunction with the blade or by the simultaneous use of a laserbeam, either through the cutting blade or applied separately.

- 2 -

South African provisional patent application no. 99/4256, also filed by the applicant in this instance, describes a cutting blade for a surgical instrument in which the cutting blade is formed of diamond and laser radiation is transmitted through the blade in order to provide a cauterisation effect along a line of incision. This earlier application is incorporated herein by reference. The laser radiation passing through the cutting blade which forms the subject of this invention would cause heating of the blade which encourages blood sticking and coagulating on the surface of the blade.

SUMMARY OF THE INVENTION

According to the invention there is provided a method of forming a protective layer of fluorine atoms on a cutting blade of a surgical instrument in which the blade is formed of hard, transparent, crystalline material, such as diamond, sapphire or garnet, the method comprising the steps of:

- a) placing the blade in a plasma reactor;
- b) plasma cleaning the blade; and
- c) coating the blade in a plasma of carbon fluoride (C_nF_m) gas.

Preferably, the carbon fluoride (C_nF_m) containing gas is C_3F_8 , alternatively C_2F_4 or C_2F_6 .

The method may include the step of chemically cleaning the blade.

Typically, the coating takes place at a pressure of 0.01 to 2 mbar, for a period of 30 to 180 minutes and at a power level of 50 to 2000 watts.

- 3 -

Conveniently, the cleaning takes place in a plasma of air, oxygen, argon or a mixture thereof.

According to a second aspect of the invention there is provided a cutting blade for a surgical instrument, the cutting blade being formed of a hard, transparent, crystalline material, such as diamond, sapphire or garnet, on the surface of which is provided a protective layer of fluorine atoms formed in accordance with the method described above.

Preferably, the blade is formed of natural, monocrystalline synthetic or polycrystalline synthetic diamond or sapphire.

According to a third aspect of the invention there is provided a method of forming a protective layer of fluorine atoms on a blade of a surgical instrument characterised in that the method comprises the step of immersing the blade into a solution of a fluoroaliphatic silyl ether.

The method is typically performed on a blade formed of diamond.

Preferably, the method includes the step of curing the layer at a temperature in excess of 200° C.

The method may include a step of forming a hydroxyl terminated surface on the blade before immersion of the blade into a solution of a fluoroaliphatic silyl ether.

The method may also include the step of forming an intermediate silicon or Ti layer on the surface of the blade prior to immersion of the blade into a solution of a fluoroaliphatic silyl ether. The Si layer preferably has a thickness less than 50 nm.

Various embodiments of the invention are described in detail in the following passages of the specification. The described embodiments are merely illustrative of how the invention might be put into effect and should not be seen as limiting on the scope of the invention.

DESCRIPTION OF AN EMBODIMENT

In general terms this invention relates to a method of forming a protective layer of fluorine atoms on a cutting blade for a surgical instrument in which the surgical blade is formed of a hard, transparent, crystalline material such as diamond, sapphire or garnet. The purpose of the layer is to reduce the sticking effect of blood and bodily fluids and materials to the blade during use. The layer should be of minimum thickness to minimise the reduction in sharpness of the blade. It is envisaged that this may be achieved according to the invention either by minimising the thickness of the layer (in the extreme case one atomic layer of fluorine) or by polishing a micro facet on one or both sides of the cutting edge after the coating has been applied.

The method of the invention is in essence a plasma coating method involving the following steps:

1. Chemically cleaning the blade.
2. Placing the cutting blade in a plasma reactor.
3. Plasma cleaning of the blade. This is done in a plasma of air, oxygen, argon or a mixture thereof for 5 to 20 minutes at approximately 1 mbar pressure and a power level of approximately 500 watts. The power is switched on at a duty cycle of 5 % to 50 % to prevent overheating. This cleaning step is essential if good adhesion of the fluorine containing layer

is to be achieved.

4. Coating the blade in a plasma of C_3F_8 . The process conditions of this coating step are a pressure of 0.01 to 2 mbar for a period of 30 to 180 minutes at a power level between 50 and 2000 watts.

The above description is a description of one method of putting the process of the invention into effect and of variations on the specific process conditions described above.

Two different approaches may be used in the process described above:

1. The chemical structure of the diamond or other hard, crystalline material is modified such that it terminates with fluorine atoms, instead of the more usual hydrogen and/or oxygen. This can be achieved by exposing the surface of the material, such as diamond, to atomic fluorine at a range of temperatures, between 273 and 573K. The preferred deposition method for the fluorine atomic layer onto the surgical blade is plasma treatment. In this method the surgical blade is exposed to a plasma excited in an atomic fluor generating substance such as SF_6 , NF_3 , HF or F_2 . Argon may be introduced into the plasma to reduce the deposition rate to controllable levels.
2. The surface is coated with a fluorocarbon polymer layer. This can be achieved by the known technique of plasma polymerization using precursors such as tetrafluoroethene. This process is described in the article entitled "Fundamentals of Plasma Chemistry and Technology" H.V. Boenig, Pub Technomatic, 1988 and the other references referred to in this document, which are all

- 6 -

incorporated herein by reference.

The preferred deposition method for the fluorocarbon polymer layer onto the surgical blade is plasma treatment. In this method the surgical blade is exposed to a plasma excited in a carbon fluoride gas. Argon may be introduced into the plasma to reduce the deposition rate to controllable levels.

The thickness of the fluorocarbon polymer layer created by this process is a function of the time for which the blade is subjected to the process. The coating thickness can vary from a few nanometers to hundreds of nanometers. Thinner coatings are more desirable so as not to blunt the cutting edge of the blade and limit laser light absorption.

The polymer is deposited from a plasma excited from one of the following gases:

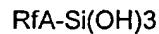
C_2F_4 , C_2F_6 , C_3F_8 .

The layer thickness is typically between 5 nanometers and 10 microns. A micro facet of between 5 and 50 microns is polished on one or both sides of the cutting edge after the layer has been formed.

In addition to the methods described above other processes may also be used to achieve the desired layer of fluorine atoms on the surface. One such method is to heat the blade in a C_2F_4 environment. This induces polymerisation of the C_2F_4 on the hot surfaces to form a layer of fluorine atoms.

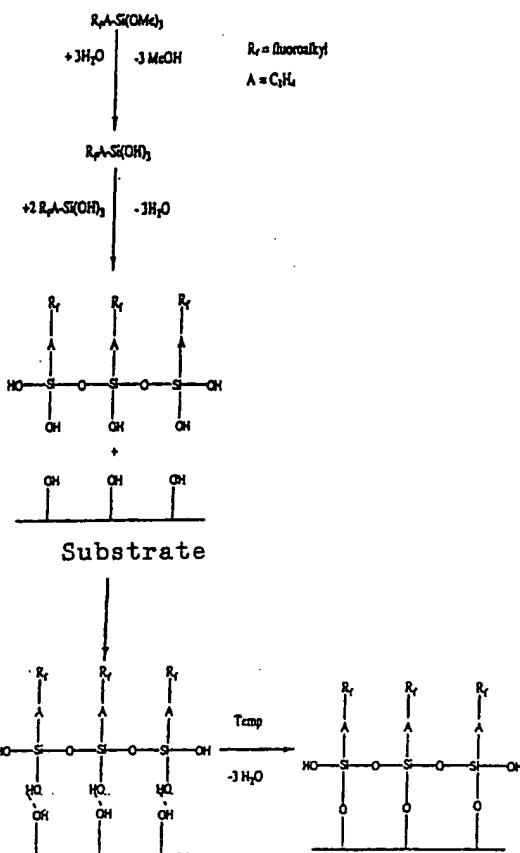
- 7 -

The layer of fluorine atoms on the surface may also be applied in other ways. For example, the fluorine atoms may be chemically bonded to the diamond surface by attaching a chemically reactive group to a fluorinated alkane group. Such a fluorinated alkane is a molecule in which fluorine atoms replace hydrogen atoms in a (usually linear) carbon chain. This is an inert molecule and a polymerised variant is the basis for the product known by the proprietary name of "Teflon". By attaching a chemically reactive group to the fluorinated alkane it can be bonded to the diamond surface. An example of such a chemically reactive group is a group containing SiOH, which can bond to a surface, which is hydroxyl (-OH) terminated. The SiOH group can bond to the hydroxyl terminated surface by splitting off a water molecule, thus forming a fluorinated tail-Si-O-Si-surface bond. An example of this type of coating material is fluoroaliphatic silyl ethers, whose generic chemical formula is given below.



A schematic representation of this reaction is provided overpage.

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where R_f is a fluorinated alkyl group, A is C_2H_4 , and Si(OH)_3 is the active bonding group. In this case one of the OH groups can bond to the surface, while the others bond to other fluoroaliphatic silyl ether molecules, thus forming a network.

An example of a fluoroaliphatic silyl ether is the product sold under the brand name FC405/60 the 3M company. Here the fluoroaliphatic silyl ether molecules are dissolved in a solvent such as an alcohol (e.g. isopropanol). By further diluting the solution with isopropanol so that a concentration of the fluoroaliphatic silyl ether molecules is obtained of less than 1% (e.g. adding 0.5 ml of coating fluid to 60 ml of isopropanol) and adding acetic acid to give a value of the pH of between 4 and 5.5, a layer of fluorine atoms can be applied to the surface of a diamond blade by dipping it in the solution for approximately 3 minutes. It is recommended that the solution

be stirred ultrasonically to establish good contact of fresh coating fluid with the surface of the blade. The blade is drawn out of the coating fluid and the remaining layer of coating solution is rinsed off with isopropanol. The coating is then allowed to cure at an elevated temperature. Although the product information supplied by the manufacturer of the fluoroaliphatic silyl ether fluid states that curing should take place for 5 minutes at 110° C, it has been found that a coating with better scratch and rubbing resistance and better adherence to the diamond blade surface can be achieved by using a temperature of 235° C for approx. 1 hour.

In respect of diamond there is an additional difficulty in chemically bonding the coating material to its surface. This is due to the fact that in general a diamond surface does not have hydroxyl groups attached to its surface. Methods of applying a hydroxyl-coated surface are therefore part of this invention. One such method achieves this by immersing the diamond blade in a bath of molten alkali hydroxide, such as sodium hydroxide or potassium hydroxide or mixtures of these with sodium- or potassiumnitrate for periods of up to one hour. Another, though less effective, method is the application of a microwave discharge in water vapour to the diamond blade surface. This dissociates water molecules and forms OH radical groups in vapour form, which can attach to the diamond surface. The discharge, however, will also generate other radical species which can attach to the surface as well, and thus occupy some bond sites, which are then not available to hydroxyl groups. This latter method results in a partially hydroxyl covered surface. Other methods include application of an interfacial layer, such as titanium (Ti), chromium (Cr). The layer can be hydroxyl terminated by immersion in dilute NaOH. It is also possible to attach the fluoroaliphatic silyl ether to the metal surface directly by dipping the freshly coated surface into the coating liquid.

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Formation of a hydroxyl-terminated Si layer can also be achieved by immersing the diamond blade in a dilute (approx. 10%) solution of NaOH in water for approx. 3 minutes at approx. 90-100° C, followed by rinsing in deionized water, dipping in a concentrated (>20%) solution of HCl in water, rinsing again in deionized water, rinsing in ethanol and finally isopropanol and then allowing the blade to dry. After this step the blade is immersed in the coating liquid and the coating is applied as described above.

The preferred manner of attaching coating molecules to a diamond surface has been to coat the surface of the diamond with a thin layer of silicon (Si). This layer, which is typically less than 50 nm thick forms a chemical bond with the diamond by the formation of SiC. A larger thickness of the Si layer is disadvantageous as it will result in a reduced transmission of the infrared radiation out of the blade and concomitant absorption of the radiation in the blade, leading to a reduced cauterising effect in the tissue and/or heating of the blade and extra sticking of tissue or blood to the blade. For applications where light is not required to exit the Si layer the layer may be applied thicker or another interfacial layer may be applied.

The cutting blades to which this process may be applied are formed of hard, transparent crystalline material. Typically this material is natural, monocrystalline synthetic or polycrystalline synthetic diamond or sapphire. However, other materials could also be used such as hard crystalline simple oxides such as zirconia (ZrO_2), yttria (Y_2O_3), garnets, most notably YttriumAluminumGarnet, LutetiumAluminumGarnet, vanadates and aluminumoxides (such as YttriumAluminumOxide.) Other hard infrared transparent crystals which may also be appropriate for the process are, orthosilicates.

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The method which forms the subject of this invention can be applied to a wide range of cutting blades operating in a range of laser wavelengths, such as those which are described in South African provisional patent application no.99/4256.

CLAIMS:

1. A method of forming a protective layer of fluorine atoms on a cutting blade of a surgical instrument in which the blade is formed of hard, transparent, crystalline material, the method comprising the steps of:
 - a) placing the blade in a plasma reactor;
 - b) plasma cleaning the blade; and
 - c) coating the blade in a plasma of carbon fluoride (C_nF_m) gas.
2. A method according to claim 1, wherein the blade is formed of diamond, sapphire or garnet.
3. A method according to either claim 1 or claim 2, wherein the carbon fluoride (C_nF_m) gas is C_3F_8 , C_2F_4 or C_2F_6 .
4. A method according to any one of the preceding claims, wherein the method includes the step of chemically cleaning the blade.
5. A method according to any one of the preceding claims wherein, the coating takes place at a pressure of 0.01 to 2 mbar, for a period of 30 to 180 minutes and at a power level of 50 to 2000 watts.
6. A method according to any one of the preceding claims, wherein the cleaning takes place in a plasma of air, oxygen, argon or a mixture thereof.

7. A cutting blade for a surgical instrument, the cutting blade being formed of a hard, transparent, crystalline material, on the surface of which is provided a protective layer of fluorine atoms formed in accordance with the method described above.
8. A cutting blade according to claim 7, wherein the cutting blade is formed of diamond, sapphire or garnet.
9. A cutting blade according to claim 7, wherein the blade is formed of natural, monocrystalline synthetic or polycrystalline synthetic diamond or sapphire.
10. A method of forming a protective layer of fluorine atoms on a blade of a surgical instrument characterised in that the method comprises the step of immersing the blade into a solution of a fluoroaliphatic silyl ether.
11. A method according to claim 10, wherein the blade is formed of diamond.
12. A method according to either claim 10 or claim 11, wherein the method includes the step of curing the layer at a temperature in excess of 200° C.
13. A method according to any one of claims 10 to 12, wherein the method includes a step of forming a hydroxyl terminated surface on the blade before immersion of the blade into a solution of a fluoroaliphatic silyl ether.

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14. A method according to any one of the preceding claims, wherein the method includes the step of forming an intermediate silicon layer on the surface of the blade prior to immersion of the blade into a solution of a fluoroaliphatic silyl ether.
15. A method according to claim 14, wherein the Si layer has a thickness less than 50 nm.